510(k) Summary

JUL 30 1998

MacroPore Protective Sheet (Protego™ System)

K972913

June 2, 1998

ADMINISTRATIVE INFORMATION

Manufacturer Name:	MacroPore, Inc. 3252 Holiday Court, Suite 223 La Jolla, CA 92037
Official Contact:	Christopher J. Calhoun Telephone (619) 458-0900 Fax (619) 458-0994
Representative/Consultant:	Floyd G. Larson Pacific Materials and Interfaces 4329 Graydon Road San Diego, CA 92130 Telephone (619) 792-1235 FAX (619) 792-1236

DEVICE NAME

Classification Name:	Plate, fixation, bone
Trade/Proprietary Name:	MacroPore Protective Sheet (Protego™ System)
Common Name:	Plating System

ESTABLISHMENT REGISTRATION NUMBER

MacroPore, Inc. has not yet obtained an Establishment Registration Number.

DEVICE CLASSIFICATION

In the Federal Register of July 2, 1982 [FR 47 page 29052], FDA proposed that bone fixation systems be classified as Class II, as shown in 21 CFR 888.3030. Although the listed Classification Name in 21 CFR is "single/multiple component metallic bone fixation appliances and accessories," the LactoSorb Trauma Plating System, a system manufactured from resorbable polymers and a predicate device for this submission, has been cleared under an expanded definition of that Classification Name. The LactoSorb device was reviewed by

the General and Plastic Surgery Device Section of the Surgical and Rehabilitation Devices Panel, and has been assigned Product Code 87HRS. We propose that MacroPore Protective Sheet (MPS), the subject of this Notification, be classified as shown above.

CONFORMANCE WITH PERFORMANCE STANDARDS

No performance standards have been established under Section 514. Voluntary standards with which the MacroPore Protective Sheet complies include American National Standards Institute (ANSI)/Association for the Advancement of Medical Instrumentation (AAMI)/ISO 11135-1994, Medical Devices - Validation and Routine Control of Ethylene Oxide Sterilization.

PACKAGING/LABELING/PRODUCT INFORMATION

MacroPore Protective Sheet will be packaged in an Ethylene Oxide (EtO) sterilizable package consisting of double heat sealed pouches, each pouch composed of a 48 gage polyester/0.002 LDPE top web and an uncoated 10739 Tyvek bottom web. Sterilization will be accomplished by ethylene oxide treatment for 6-6.5 hours at 7-9 psig in 10% EtO/90% HCFC. Sterilization will be validated using ANSI/AAMI/ISO 11135-1994, Medical Devices - Validation and Routine Control of Ethylene Oxide Sterilization. The sterility assurance level (SAL) that MacroPore intends to meet for the MacroPore Protective Sheet is 10^{-6}. The device is not represented to be "pyrogen free."

INTENDED USE

MacroPore Protective Sheet (MPS) is intended for use in trauma and reconstructive procedures in the midface and craniofacial skeleton:

1. Comminuted fractures of the naso-ethmoidal and infraorbital areas
2. Comminuted fractures of the frontal sinus wall
3. Trauma of the midface or craniofacial skeleton
4. Reconstructive procedures of the midface or craniofacial skeleton.

The system is not intended for use in the mandible and/or for full load bearing procedures.

DEVICE DESCRIPTION

Design Characteristics

MacroPore Protective Sheet is an absorbable, macroporous implant in sheet form manufactured from polylactic acid (PLA). The purpose of the sheet is to provide fixation of non-load bearing bone defects in the cranio-facial area of the mammalian skeletal system.

MPS can be cut with scissors, is thermoplastic when heated to 55 C (for example, by the use of sterile hot water) and thus can be conformed three dimensionally to any bone defect. It can be rolled into a tube or used as a flat sheet. It can be used in conjunction with internal bone fixation devices such as plates and screws which can be also used to fixate the MPS and prevent dislocation. The system includes a selection of resorbable screws and tacks.

MPS is provided in sheets of 40 x 40 mm and in premanufactured shapes and can be provided in other sizes as needed for particular surgical procedures. Its thickness ranges from 500 microns to 1000 microns according to the defect to be treated. The pore size ranges from 500 microns to 2000 microns with pores distributed uniformly throughout the sheet in an offset or aligned pattern.

Material Composition

MPS is fabricated from poly(L-lactide-co-D,L-lactide) 70:30.

EQUIVALENCE TO MARKETED PRODUCT

MacroPore Protective Sheet shares indications and design principles with the following predicate devices, each of which has been determined by FDA to be substantially equivalent to pre-amendment devices: LactoSorb Trauma Plating System from W. Lorenz, a unit of Biomet, Inc. (K960988, K955729), Tilghman Titanium Mesh Skeletal Orbit Liner from TiMesh, Inc. (K922308), Motech Titanium Mesh from Biedermann MOTECH GmbH (K900138), and Leibinger Titanium DynamicMesh.

Intended Use

The indications for use of MacroPore Protective Sheet (MPS) are not new indications in that they are the same as or are included in those for the predicate devices. MPS is intended for use in the craniofacial skeleton for fracture fixation and fixation in surgical reconstruction. Specific indications are:

> for use in trauma and reconstructive procedures in the midface and craniofacial skeleton (comminuted fractures of the naso-ethmoidal and infraorbital areas, comminuted fractures of the frontal sinus wall, trauma of the midface or craniofacial skeleton, reconstructive procedures of the midface or craniofacial skeleton).

The system is not intended for use in the mandible and/or for full load bearing procedures.

The predicate devices share intended uses with MPS as follows: The LactoSorb Trauma Plating System and the titanium mesh products have identical intended uses with regard to fracture fixation to those of MPS with a thickness of 1000 microns.

Design and Materials

The design and functional characteristics of MacroPore Protective Sheet and the predicate devices are similar. The physical designs of MPS and the LactoSorb device both consist of a thin sheet with perforations. The LactoSorb Trauma Plating System is made from a copolymer of polylactic acid and polyglycolic acid and has low crystallinity. The composition and processing of LactoSorb devices are selected to permit 70% of its strength to be maintained *in vivo* for 6-8 weeks (sufficient time to facilitate fracture fixation), yet to degrade and be cleared from the body within 9 to 15 months. The poly(L-lactide-co-D,L-lactide) 70:30 of which MPS is made has been shown in animal studies to degrade more slowly, and to be fully degraded after 36 months. Both Lacrosorb and MPS are essentially amorphous. It is believed that degradation of an amorphous matrix is less likely than that of a crystalline matrix to leave microscopic undegraded crystalline regions. Such material could cause osteolysis in the same way as does the polyethylene debris that results from wear of articulating surfaces.

SUMMARY: TABLE OF SUBSTANTIAL EQUIVALENCE

MacroPore Protective Sheet is substantially equivalent to the LactoSorl Liner, Motech Titanium Surgical Mesh and Titanium Dynamic Mesh ir

	Subject Device	
	MacroPore Protective Sheet	LactoSorb Trauma System (K960988, K955
INTENDED USE	For use in trauma and reconstructive procedures in the midface and craniofacial skeleton 1. Comminuted fractures of the naso-ethmoidal and infraorbital areas 2. Comminuted fractures of the frontal sinus wall 3. Trauma of the midface or craniofacial skeleton 4. Reconstructive procedures of the midface or craniofacial skeleton	For use in trauma an reconstructive proce the midface and crani skeleton 1. Comminuted frac the naso-ethmoid infraorbital areas 2. Comminuted frac the frontal sinus 3. Trauma of the mi craniofacial skele 4. Reconstructive p of the midface or craniofacial skele
DESIGN	Sheet of 500 and 1000 microns thickness, size 60 x 80 mm or as required, with pores of 500 to 2000 microns diameter arranged in a uniform offset or aligned pattern	Sheets of 500 and 10 microns thickness, si 25 mm to 50 x 50 mr pores of 1500 to 200 microns diameter arr a uniform aligned pat
MATERIAL	poly(L-lactide-co-D,L-lactide) 70:30 (Resomer® LR 708), amorphous	poly(L-lactide-co-gly 82:18, low crystallini

) Trauma Plating System, Tilghman Titanium Mesh Skeletal Orbit
1 the following respects:

	Predicate Devices		
Plating 729)	Tilghman Titanium Mesh Skeletal Orbit Liner (K922308)	Motech Titanium Surgical Mesh (K900138)	Titanium Dynamic Mesh
d dures in ofacial tures of al and tures of wall dface or ton rocedures ton	For use in orbital bony defect repair/ reconstruction	For use in reinforcing weak bony tissues such as in acetabular cups, ... and reconstruction of oral-maxillo-cranio-facial surgeries	For defect-bridging reconstruction of non-loadbearing bony structures
00 es 25 x n, with 0 nged in tern	Sheets formed to various shapes	Sheets of 1000 microns thickness, formed to various shapes	Sheets of 300 to 600 microns thickness, sizes of 40 x 40 mm to 90 x 90 mm, with open hole pattern, including screw holes of 1.0 mm to 2.3 mm
colide) ty	Titanium	Titanium	Titanium

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 30 1998

MacroPore, Inc.
c/o Pacific Materials and Interfaces
Mr. Floyd G. Larson
4329 Graydon Road
San Diego, California 92130

Re: K972913
Trade Name: Macropore Protective Sheet (Protego System)
Regulatory Class: II
Product Code: HRS and HWC
Dated: June 5, 1998
Received: June 8, 1998

Dear Mr. Larson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K972913

Device Name: MacroPore Protective Sheet

Indications for Use:

MacroPore Protective Sheet (MPS) is intended for use in trauma and reconstructive procedures in the midface and craniofacial skeleton:

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use ____

[redacted] Sign-Off

[redacted] General [redacted] Devices K972913

[redacted] 510(k) Number